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GUEST EDITORIAL

Stereotactic Breast Biopsy: Who Should Perform It?

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The widespread utilization of screening mammography in this country has been a major positive step in breast cancer control through earlier detection. The subject of breast cancer and mammography receives considerable public attention and scrutiny. This no doubt has contributed to a federal legislative response to public concern about the quality of screening mammography. The American College of Radiology was sensitive to this issue and established a voluntary accreditation program in 1987. It became obvious that quality improvement in screening mammography was wanting since only about 40% of 10,000 facilities performing screening mammography initially were able to meet the requirements set forth by the American College of Radiology.

Congress passed the Mammography Quality Standards Act (MQSA) in 1992 and designated the U.S. Food and Drug Administration (FDA) as the federal agency responsible for the development of regulations pertaining to screening mammography. The Act established several requirements aimed at strengthening mammography quality, including the requirement of accreditation and annual inspection of mammography facilities. Specifically, MQSA required that the FDA establish quality standards for mammography equipment, personnel, and practices; that all mammography facilities be accredited by an FDA-approved accrediting body once every 3 years and obtain a certificate from the FDA in order to legally provide mammography services; and that all mammography facilities have an annual evaluation by a qualified medical physicist and an annual inspection by FDA inspectors that includes a test of image quality. Currently the American College of Radiology is responsible for at least 95% of the accreditation work load.

Measures of success from this Act have been reported. Before the Act took effect, 11% of facilities tested were unable to pass image quality tests; the national figure is now approximately 2%. The percentage of facilities that passed the American College of Radiology's accreditation on the first attempt increased from 66% in 1995 to 82% in 1997 [1].

Interventional mammography is included under the MQSA and is defined as stereotactic core needle biopsy, mammographically directed open surgical biopsy, and galactography. Ultrasound-guided biopsy is not included under the Act. Only recently has the FDA completed the task of developing regulations for screening mammography and shifted attention to interventional radiology. Surgeons had little or no interest or knowledge of the MQSA as it pertained to screening mammography, but are obviously interested in potential regulations related to interventional radiology. We are, after all, now dealing with a breast biopsy.

The evaluation and the management of breast disease occupy a major portion of the training and practice profile of general surgeons. Surgeons possess the skills necessary to assess risk, perform skillful breast examinations, understand benign and malignant breast diseases, assess the indications and proper approach for breast biopsy, and counsel patients and their families about benign and malignant breast disease. Finally, they are responsible for the surgical management of these diseases and for appropriate follow-up surveillance.

Why don't all surgeons who are performing breast biopsies for palpable lesions or occult lesions through needle localization techniques, then, perform stereotactic breast biopsy? There are no reliable data available to tell us how many surgeons are performing stereotactic breast

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biopsy, but some self-selected subset is represented. I am personally acquainted with many surgeons in this country who have a major interest in breast cancer and are not performing this procedure. The most common reasons cited for this are lack of available time to learn and perform the procedure or no interest in getting involved with imaging techniques. There is a significant number of surgeons, however, who possess an interest in performing this procedure. Many are most likely ''breast surgeons'' devoting all of their practice to this area, but it is my impression that many general surgeons who commit 20–40% of their practice to the breast are interested in or doing stereotactic breast biopsy.

Surgeons should and do develop a personal practice profile based on training, volume, results, confidence, and comfort level. I suspect that many surgeons do not perform stereotactic breast biopsy because they are not comfortable working with something they have not been trained to work with, i.e., imaging equipment. Motivated surgeons can learn to be comfortable with this equipment. They must always make a decision about whether to get involved with new emerging technology, such as laparoscopy or sentinel node biopsy.

Likewise, should all radiologists perform stereotactic breast biopsy? They have self-selected much in the same way as surgeons have. Motivated radiologists can and have acquired the clinical skills beyond image interpretation which are necessary for the performance of stereotactic breast biopsy. These skills include breast physical examination, risk assessment, a thorough understanding of benign and malignant breast diseases, a solid foundation in breast surgical pathology, and an interest and ability to communicate with patients and their families regarding approaches to diagnosis and results.

I believe that the patient's best interests are served by a collaborative approach in which the skills of both the radiologist and surgeon are put to advantage. There are numerous examples of facilities in this country in which the Departments of Surgery and Radiology work in a collegial environment. In our institution and many others, the patient is seen in a Breast Center with geographic proximity between the surgeon and radiologist. Who performs the procedure is less important than having the skills of both specialists available to the patient.

The less prevalent model in this country is an independent radiology or surgical center. The personnel and equipment in such independent settings must meet the same standards as a collaborative practice in order to provide quality patient care. Such centers will be staffed by self-selected surgeons who have acquired imaging and targeting skills or radiologists who have acquired clinical skills. This sounds rational but how is a woman with a newly diagnosed mammographic abnormality supposed to decide where to go for help? How can she be sure that she will be dealing with a physician with the necessary qualifications? Will she feel assured if there is some type of regulatory process in place as in screening mammography or a voluntary accreditation program?

Both the American College of Surgeons and the American College of Radiology believe that there is a need for common standards pertaining to stereotactic breast biopsy and that these standards and accreditation of physicians and facilities should be voluntary, rather than regulated by the FDA. The American College of Radiology already has a voluntary accreditation program for stereotactic breast biopsy and recently the Board of Regents of the American College of Surgeons unanimously approved the concept of voluntary accreditation by the American College of Surgeons for stereotactic breast biopsy. Both Colleges have communicated with the FDA urging the agency to allow voluntary accreditation rather than require federal regulation.

The challenge, then, lies before us. Surely the FDA will not be satisfied with a voluntary accreditation program in which there is anything less than full participation by facilities and physicians. The onus is now on the Colleges to delineate the key personnel requirements and equipment standards for stereotactic breast biopsy performed in either a collaborative setting or an independent setting. It is a daunting task to design a set of standards for two divergent specialties in medicine practicing in a diverse environment. Nonetheless, an initial attempt was made through a Joint Task Force of the two Colleges and published through the respective College's venues. This document was recently discussed extensively by the National Mammography Quality Assurance Advisory Committee to the FDA based on broad surgical and radiologic feedback. The views expressed by the National Mammographic Quality Assurance Advisory Committee will result in significant revision of the original document.

Keep in mind that we are dealing with a transitional phase in which new technology has been introduced into the practicing community. This requires educational courses to teach new skills to surgeons and radiologists. But stereotactic breast biopsy is becoming an intricate part of training programs in radiology and surgery. Eventually, physicians will be deemed qualified to perform stereotactic breast biopsy by virtue of Board certification, much in the same way that radiologists are now MQSA certified by virtue of their training and certification. I would cite laparoscopy, particularly laparoscopic cholecystectomy, as an example of emerging technology that

became a standard of care in this country. Multiple laparoscopic cholecystectomy courses brought practicing surgeons up to standard. Now graduates of surgical residency programs can be certified to perform the procedure by virtue of their training. Laparoscopic cholecystectomy courses are rare because the need for them no longer exists.

In the final analysis we should set aside turf issues and focus on quality patient care. Success will most likely follow if we remember this guiding principle and be accountable for our results through a well-organized voluntary effort.

REFERENCE

1. Mammography Services: Impact of federal legislation on quality, access and health outcomes. U.S. General Accounting Office Report to Congressional Committees, October 1997. Publication No. GAO/HEHS-98–11.